



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
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VIA FEDERAL EXPRESS

May 3, 2004

WARNING LETTER

Steven L. Snodgrass, M.D.
Chief Executive Officer
Peak Performance Foods, LLC
Hartland Place
996 Wilkinson Trace, Unit B-3
Bowling Green, Kentucky 42103

Dear Dr. Snodgrass:

On January 22, 2004 the Food and Drug Administration (FDA) collected samples of your PRO BITES® products (Sour Cream and Onion, Bar-B-Que, Nacho Cheese, and Ranch flavors). We have reviewed your labeling for these products and determined that the products are misbranded in violation of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. § 321 *et seq.*) and Title 21 of the Code of Federal Regulations (21 CFR), Part 101- Food Labeling. The following deviations were found:

Your PRO BITES® products bear the label claim "This revolutionary food ... fights obesity," which suggests that the products are intended to cure, mitigate, treat, or prevent disease. This claim establishes that the products are drugs within the meaning of Section 201(g)(1)(B) of the Act (21 U.S.C. § 321(g)(1)(B)) because they are intended for use in the cure, mitigation, treatment, or prevention of a disease, i.e., obesity. Because these products are not generally recognized as safe and effective for their intended use, the products are new drugs under section 201(p) of the Act (21 U.S.C. § 321(p)). New drugs may not be legally marketed in the United States without approved New Drug Applications (21 U.S.C. § 355(a)). Furthermore, these products are also misbranded within the meaning of Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use (21 U.S.C. § 352(f)(1)).

Your products are misbranded under section 403(a)(1) of the Act (21 U.S.C. § 343(a)(1)) because their labels bear the claim "LOW CARB" (meaning low in carbohydrate). Section 403(a)(1) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. In determining whether labeling is misleading, the Agency takes into account representations made or suggested by statements in the labeling, among other things (*see* section 201(n) of the Act (21 U.S.C. § 321(n)). A comparison of the carbohydrate content of your products to comparable products, based upon the reference amount customarily consumed (RACC) of 30 grams (g) (*see* 21 CFR 101.12(b)) for these types of products, reveals that they contain the same or similar amounts of carbohydrate. For example, the amount of total carbohydrate per RACC in your PRO BITES® Sour Cream and Onion, Nacho Cheese, and Ranch products is 7.5 g, and 9.6 g in your PRO BITES® Bar-B-Que product, compared to a range of 0-13.5g in comparable commercial products. Thus, these products are not lower

in carbohydrate than other comparable commercial products. Consequently, the "LOW CARB" claim is false and misleading and therefore violates section 403(a)(1) of the Act.

Your products are further misbranded under section 403(r)(1)(A) of the Act because the use of "LOW FAT" on the principal display panel fails to comply with the regulation defining this nutrient content claim. "Low fat" is defined by regulation to mean that a food with a RACC of 30 g or less contains 3 g or less of fat per RACC (21 CFR 101.62(b)(2)). The RACC for this type of product is 30 g (21 CFR 101.12(b)). The nutrition information on these products indicates that your Sour Cream and Onion and Nacho Cheese flavored PRO BITES® products contain 4.5 g of fat per 28 g serving of the food, which would result in approximately 4.8 g of fat per RACC. Your Ranch and Bar-B-Que flavored PRO BITES® products contain 4.0 g of fat per 28 g serving of the food, which would result in approximately 4.3 g of fat per RACC. Therefore, because each of these products exceeds 3 g of fat or less per RACC, these products do not qualify for the "low fat" nutrient content claim.

Further, because these products are not "low fat," they are misbranded under section 403(a)(1), because the "low fat" claim is false and misleading.

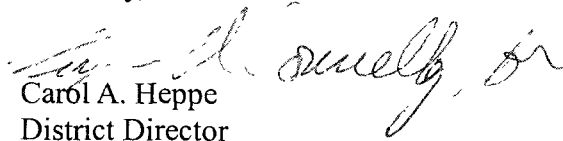
Finally, your products are misbranded under section 403(q)(1)(A)(i) and (q)(1)(B) because the serving size and servings per container declared on the Nutrition Facts panel are not declared in accordance with the requirements for serving size. A product that is packaged and sold individually and that contains less than 200 percent of the applicable RACC (where the RACC is less than 100 grams) must be considered a single-serving container and the entire content of the product must be labeled as one serving, in accordance with 21 CFR 101.9(b)(6). Your PRO BITES® products are packaged and sold individually. According to the label on your products, a package contains a total of approximately 45 grams (1.6 oz.) of product. This amount is less than 200 percent of the 30 g RACC for snack foods, which is 60 g. Therefore, the Nutrition Facts panel on your products must declare the serving size as one package and all of the nutrition information declared must be based on the total amount of product in the package.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that your products comply with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective actions cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Stephen J. Rabe, Compliance Officer, 6751 Steger Drive, Cincinnati, OH 45237. If you have questions regarding any issues in this letter, please contact Mr. Rabe at 513-679-2700, extension 163.

Sincerely,


Carol A. Heppe
District Director